Technology Appraisal Committee Meeting (Committee A)

Minutes: [Confirmed]

Date and Time: Tuesday 16 January 2018

Venue: Prospero House, 241 Borough High Street, SE1 1GA

Present:
1. Chair Jane Adam Present for all notes
2. Professor Iain Squire Present for all notes
3. Dr Graham Ash Present for all notes
4. Dr Jeremy Braybrooke Present for all notes
5. Dr Justin Daniels Present for all notes
6. Dr Rachel Hobson Present for all notes
7. Professor John McMurray Present for notes 7 to 39
8. Dr Mohit Sharma Present for all notes
9. Dr Ian Bernstein Present for all notes
10. Dr Minal Bikhai Present for all notes
11. Mrs Pamela Rees Present for all notes
12. Mrs Ellen Rule Present for all notes
13. Mr Stephen Sharp Present for all notes
14. Dr Brian Shine Present for all notes
15. Mr David Evans Present for all notes
16. Dr John Watkins Present for all notes
17. Professor Olivia Wu Present for all notes
18. Dr Nery Woolacott Present for notes 7 to 39
19. Dr Rita Faria Present for notes 7 to 39

In attendance:

Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for all notes

Janet Robertson Associate Director, National Institute for Health and Care Excellence Present for all notes

Thomas Feist Project Manager, National Institute for Health and Care Excellence Present for all notes

Marcia Miller Technology Appraisal Administrator, National Institute for Health and Care Excellence Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Presented</th>
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</thead>
<tbody>
<tr>
<td>Irina Voicechovkaja</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 1 to 17</td>
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<tr>
<td>Zoe Charles</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>Present for notes 1 to 17</td>
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<tr>
<td>Marcela Haasova</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 18 to 27</td>
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<tr>
<td>Joanna Richardson</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>Present for notes 18 to 27</td>
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<tr>
<td>Eleanor Donegan</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>Present for notes 28 to 39</td>
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**NHS England**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Presented</th>
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<tbody>
<tr>
<td>Peter Clark</td>
<td>NHS England, Clinical Expert</td>
<td>Present for all notes</td>
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**Evidence Review Group**

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Presented</th>
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<tbody>
<tr>
<td>Dr Steve Edwards</td>
<td>BMJ-TAG</td>
<td>Present for notes 1 to 13 &amp; 18 to 24</td>
</tr>
<tr>
<td>Tracey Jhita</td>
<td>BMJ-TAG</td>
<td>Present for notes 1 to 13</td>
</tr>
<tr>
<td>Charlotta Karner</td>
<td>BMJ-TAG</td>
<td>Present for notes 1 to 13</td>
</tr>
<tr>
<td>Victoria Wakefield</td>
<td>BMJ-TAG</td>
<td>Present for notes 18 to 24</td>
</tr>
<tr>
<td>Peter Cain</td>
<td>BMJ-TAG</td>
<td>Present for notes 18 to 24</td>
</tr>
<tr>
<td>Adrian Bagust</td>
<td>Liverpool Reviews Implementation Group (LriG)</td>
<td>Present for notes 28 to 36</td>
</tr>
<tr>
<td>Name</td>
<td>Role and Affiliation</td>
<td>Notes Present For</td>
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<tr>
<td>Nigel Fleeman</td>
<td>Liverpool Reviews Implementation Group (LriG)</td>
<td>Present for notes 28 to 36</td>
</tr>
<tr>
<td>Dr Andrew Clamp</td>
<td>Consultant and Senior Lecturer in Medical Oncology</td>
<td>Present for notes 1 to 13</td>
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<tr>
<td>Dr Sarah Williams</td>
<td>Consultant Medical Oncologist</td>
<td>Present for notes 1 to 13</td>
</tr>
<tr>
<td>Dr Guy Faust</td>
<td>Consultant Medical Oncologist</td>
<td>Present for notes 18 to 24</td>
</tr>
<tr>
<td>Dr Hilary Morrison</td>
<td>Retired GP</td>
<td>Present for notes 1 to 13</td>
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<tr>
<td>Ms Rebecca Rennison</td>
<td>Director of Public Affairs and Services</td>
<td>Present for notes 1 to 13</td>
</tr>
<tr>
<td>Ana Uribe-Echeverry</td>
<td>NICE, Corporate Office</td>
<td>Present for all notes</td>
</tr>
<tr>
<td>Henry Edwards</td>
<td>NICE, CDF Team</td>
<td>Present for notes 1 to 27</td>
</tr>
<tr>
<td>Heidi Livingstone</td>
<td>NICE, PPIP</td>
<td>Present for notes 1 to 17</td>
</tr>
<tr>
<td>Emma Kent</td>
<td>NICE</td>
<td>Present for notes 18 to 27</td>
</tr>
<tr>
<td>Adam Storrow</td>
<td>NICE</td>
<td>Present for all notes</td>
</tr>
<tr>
<td>Michael Wallington</td>
<td>PHE National Cancer Registration and Analysis Service</td>
<td>Present for notes 1 to 39</td>
</tr>
<tr>
<td>Catherine Thomson</td>
<td>PHE National Cancer Registration and Analysis Service</td>
<td>Present for all notes 1 to 39</td>
</tr>
<tr>
<td>Frances Adlam</td>
<td>NICE, Press Office</td>
<td>Present for notes 1 to 17</td>
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Notes

Welcome

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer [ID1041]

2. The Chair informed the Committee there were non-public observers present.

3. Apologies were received from Mrs Sarah Parry.

Notes from the last meeting

4. Minutes of the last meeting were agreed.

Appraisal of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer [ID1041]

Part 1 – Open session

5. The Chair welcomed the invited experts: Dr Andrew Clamp, Dr Steve Edwards, Tracey Jhita, Charlotte Karner, Hilary Morrison, Rebecca Rennison and Dr Sarah Williams to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Tesaro to the meeting.

7. The Chair asked all Committee members to declare any relevant interests

7.1. Dr Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Minal Bakhai Dr Justin Daniels, Mr David Evans, Dr Rita Faria, Dr Rachel Hobson, Professor John McMurray, Dr Mohit Sharma, Dr Ian Bernstein, Ms Pamela Rees, Ms Ellen Rule, Mr Stephen Sharp, Dr Brain Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Mr Stephen Sharp all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer
7.2. Dr Jeremy Braybrooke, non-personal specific financial interest as he is co-investigator on a clinical trial in breast cancer with a comparator, olaparib.

7.2.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting.

7.3. Mr Adrian Griffith declared a personal specific financial interest as his employer Janssen (owned by J&J) has a global collaboration agreement with Tesaro for Niraparib in prostate cancer (but not ovarian cancer).

7.3.1 It was agreed that this declaration would prevent Mr Adrian G Griffin from participating in this section of the meeting and he remained absent from the meeting.

7.4. Dr Paul Robinson declared a personal specific financial interest as his employer, MSD, has entered into a collaboration with AstraZeneca to co-develop olaparib, the comparator agent.

7.3.1 It was agreed that this declaration would prevent Dr Paul Robinson from participating in this section of the meeting and he remained absent from the meeting.

8. The Chair asked all NICE Staff to declare any relevant interests.

8.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer.

9. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.

9.1. Dr Steve Edwards, Tracey Jhita, Charlotte Karner, Hilary Morrison and Rebecca Rennison declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer.

9.2. Dr Andrew Clamp declared a personal specific financial interest as he has been paid for advisory boards, research funding by AstraZeneca and conducted clinical trials of PARP inhibitors sponsored by AstraZeneca, comparator manufacturer for this appraisal.

9.2.1. It was agreed that this declaration would not prevent Dr Andrew Clamp from participating in this section of the meeting.

9.3. Dr Sarah Williams declared a personal specific financial interest as she been paid for attending an advisory board hosted by Tesaro in March 2017. She has also has been a co-investigator in the NOVA study, she
has been a co-investigator in Olaparib studies in ovarian cancer and has received conference funding from AstraZeneca

10. The Chair introduced the lead team, Dr Jeremy Braybrooke, Pamela Rees and Ellen Rule who gave presentations on the clinical effectiveness and cost effectiveness of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer.

11. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

12. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.

13. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

14. Discussion on confidential information continued. This information was supplied by the company.

15. The Committee continued to discuss the clinical and cost effectiveness of Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer.

16. The committee decision was based on consensus.

17. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.
Appraisal of Avelumab for treating metastatic Merkel cell carcinoma [ID1102]

Part 1 – Open session

18. The Chair welcomed the invited experts: Dr Steve Edwards, Dr Guy Faust Peter Cain and Victoria Wakefield to the meeting and they introduced themselves to the Committee.

19. The Chair welcomed company representatives from Merck to the meeting.

20. The Chair asked all Committee members to declare any relevant interests

20.1. Dr Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Minal Bakhai, Dr Jeremy Braybrooke, Dr Justin Daniels, Mr David Evans, Dr Rita Faria, Dr Rachel Hobson, Professor John McMurray, Dr Mohit Sharma, Dr Ian Bernstein, Ms Pamela Rees, Ms Ellen Rule, Mr Stephen Sharp, Dr Brain Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Mr Stephen Sharp all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Appraisal of Avelumab for treating metastatic Merkel cell carcinoma.

20.2. Dr Paul Robinson declared a personal specific financial interest as his employer, MSD, has entered a phase III data with pembrolizumab in merkle cell carcinoma, so although not listed as a comparator, he made the decision to remain absent from the meeting.

21. The Chair asked all NICE Staff to declare any relevant interests.

21.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Avelumab for treating metastatic Merkel cell carcinoma.

22. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

22.1. Dr Steve Edwards, Peter Cain, Victoria Wakefield and Dr Guy Faust declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the
technologies to be considered as part of the appraisal of Avelumab for treating metastatic Merkel cell carcinoma.

22.2. Dr Guy Faust declared a personal non-specific financial interest as he is a clinical expert consultant medical oncologist.
22.2.1. It was agreed that this declaration would not prevent Dr Guy Faust from participating in this section of the meeting.

22. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.

23. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

24. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.

25. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

**Part 2 – Closed session**

26. Discussion on confidential information continued. This information was supplied by the company.

27. The Committee continued to discuss the clinical and cost effectiveness of Avelumab for treating metastatic Merkel cell carcinoma.

27.1. The committee decision was based on consensus.

28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.
Part 1 – Open session

28. The Chair welcomed the invited experts: Adrian Bagust and Nigel Fleeman to the meeting and they introduced themselves to the Committee.

29. The Chair welcomed company representatives from Eisai to the meeting.

30. The Chair asked all Committee members to declare any relevant interests

30.1. Dr Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Minal Bakhai, Dr Jeremy Braybrooke, Dr Justin Daniels, Mr David Evans, Dr Rita Faria, Dr Rachel Hobson, Professor John McMurray, Dr Mohit Sharma, Dr Ian Bernstein, Ms Pamela Rees, Ms Ellen Rule, Mr Stephen Sharp, Dr Brain Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Mr Stephen Sharp all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen.

31. The Chair asked all NICE Staff to declare any relevant interests.

31.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen.

32. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

32.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen.

33. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
34. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

35. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.

36. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

37. Discussion on confidential information continued. This information was supplied by the company.

38. The Committee continued to discuss the clinical and cost effectiveness of Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen.

38.1. The committee decision was based on consensus.

39. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Date, time and venue of the next meeting

40. Tuesday 13 February 2018, 10am at Prospero House, 241 Borough High Road, SE1 1GA